American Association of Exporters and Importers

1200 G Street, NW, Suite 800, Washington, DC 20005

July 12, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Docket No. 2002N-0278 – Prior Notice of Imported Food**

Dear Sir/Madam:

For more than 80 years the American Association of Exporters and Importers (AAEI) has been a national voice of American business in support of fair and open trade among nations. AAEI's expertise in international trade and customs matters is widely recognized in Washington and other national capitals. AAEI is the only national association dedicated exclusively to representing the interests of both U.S. exporters and importers before U.S. government agencies, Congress, international organizations, and foreign governments. Accordingly, it is with pleasure that AAEI provides the U.S. Food and Drug Administration (FDA) with its comments in connection with the re-opening of the comment period on the Interim Final Rule on Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness Act of 2002 (the "Act"), published on April 14, 2004 [Federal Register: Volume 69, Number 72, Pages 19763-19765].

Description of AAEI

AAEI's members include manufacturers, distributors, and retailers of a broad spectrum of products including chemicals, electronics, machinery, footwear, automobiles and automotive parts, food, household consumer goods, toys, specialty items, textiles and apparel, and footwear. AAEI membership also comprises organizations serving the international trade community such as carriers, customs brokers, freight forwarders, banks, attorneys, and insurance firms. AAEI's large and diverse membership base provides it with credibility among policy makers. As a prominent representative of the U.S. international trade community, and of both importers and exporters, AAEI is able with particular effectiveness to make the point that trade restrictions and protectionism ultimately injure the world's largest consumer market and the world's largest exporter: the United States.

Overview

AAEI acknowledges the value of the recent steps taken by the Food and Drug Administration in its educational outreach efforts to the trade industry through scheduled trade education sessions, port-specific flyers, foreign government training and website communications that summarize certain compliance data. We recognize the importance of these outreach efforts and applaud the unprecedented efforts the FDA has made in this regard. We also support and encourage the continuation of this effort for both this and future proposed regulations. AAEI firmly believes that more communication between the trade community and government agencies such as the FDA, especially in that critical time between the enactment of a statutory requirement and the actual publication of a notification of proposed rulemaking, is essential to the development of workable, efficient and cost effective regulations that protect the borders of the United States while still allowing the uninterrupted flow of legitimate trade. In addition, now that the importing community has actual experience with the systems, timeframes and outlined data elements, we appreciate the opportunity to provide additional feedback on all aspects of the Prior Notice interim final rule. Our intent is to provide relevant and useful feedback about the implementation process to date, as well as to respond to the specific questions outlined in the Federal Register notice.

Implementation Process

As critical partners in the continued health of the U.S. economy, one of the trade community's primary goals is to maintain efficient and effective supply chains while fully supporting the important security mandates outlined under the Bioterrorism Act. A critical tool in achieving this goal is a workable, phased-in approach to full enforcement of the Prior Notice requirements that allows for the necessary time and training to occur for both importers and government officials under a new and relatively untested system. That requested phased-in approach was outlined as part of the FDA's Compliance and Policy Guide for FDA and CBP staff published in December of 2003. Under the guidelines the FDA stated its intent to provide a transition period, during which it would emphasize education about the Prior Notice requirements to help industry achieve compliance with the regulation. Of special importance was the intent to gather data to track compliance with the Prior Notice requirements and to use that data and summary information to assist the trade industry as a whole, as well as individual companies, in improving the submission of Prior Notice data.

Importers Should Be Apprised of Specific Submission Errors. FDA indicated that appropriate data related to specific errors for an individual entity's submissions would be tracked within the new system, and that during the first two enforcement phases the information, in the form of a written communication from the FDA to the importer and/or

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its broker, would be provided to allow the importer time to fix any systems or process issues that may exist in regards to their current submission processes. Due to the increased scope of the Prior Notice data elements and the IFR required time frames, potential submission issues could result from one or more sources (manufacturer, carrier, broker and/or importer of record) depending on the error recorded. For example, if the error recorded is "no estimated carrier information submitted," such a process issue may lie with the importer's carrier and/or broker. If the error is "no registration number," the problem may lie with the manufacturer and/or importer of record. If the error is "not timely submitted," then the process issue lies with the carrier and/or broker. For the majority of importers who use multiple carriers, a specific problem might rest with one of many carriers. It is critical that specific errors are promptly relayed back to importers in order for the phased-in process to translate into an "uninterrupted flow of food imports" in August 2004.

While AAEI's members appreciate the summary information that has been published on the FDA's website and are able to use this information as a general guide as to how the process is working overall, to-date it does not assist affected companies in identifying individual company process gaps that would allow a for proactive approach to fixing those gaps and ensuring as efficient a submission process as possible. In effect, without the company-specific information the FDA had indicated it would provide, importers are not able to anticipate problems and develop cooperative solutions. The resulting potential for multiple rejections and high congestion at the borders is, unfortunately, virtually unavoidable.

In addition, multiple other systems issues have been identified that further reduced the effectiveness of the Phase I and Phase II enforcement timeframes. Identified issues include Prior Notice sent without entry using an in-bond number procedure, the ability to disclaim a Prior Notice on FD3 shipments and the process for claiming Prior Notice on any tariffs other than FD0 shipments.

Full Enforcement Should Be Delayed. AAEI understands that the inability to provide the critical company-specific information outlined above and/or resolution to the other outlined systems problems is the result of required FDA/CBP systems upgrades that has not yet been completed. As such, AAEI strongly urges that the full enforcement deadline of August 12, 2004 be extended to such a time that the FDA feedback requirements outlined in Phase I and Phase II of the guidance documents are actually available to the trade and the required process changes may occur. FDA and CBP should continue to expect that firms and individuals demonstrate a good faith effort at compliance while the transitional policy remains in place. Clearly, we all agree that failure to submit Prior Notice should be fully enforced as of August 12. The issue is how to handle incomplete or inaccurate submissions. The obvious alternative to a deadline extension is that individual companies will only find out about their company's specific process issues through multiple rejections at the border. AAEI believes that this solution is not workable either for industry or the FDA.

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We note also that importers continue to receive conflicting information as to the enforcement guidelines at individual crossing points and/or from individual enforcement officers of both the FDA and CBP. The extension of the full enforcement date would allow the FDA and CBP to upgrade their current training efforts with the officers at all ports of entry so that uniform and consistent enforcement occurs.

AAEI understands that full enforcement must occur and that the deadlines cannot be extended indefinitely. However, we firmly believe and urge that an extension must occur at this time in order for these implementation issues to be appropriately considered and resolved. It works against the operations of the FDA if conflicting information is given out by its personnel. It undermines FDA's operations, as well, if companies are not able quickly and clearly to identify the source of submission irregularities. Most importers are honest and seek to be compliant for one simple but important reason – they recognize that by doing so they are able to bring their product to market more quickly and at less cost. FDA is in a similar position. The smoother the process, the less pressure is put on the agency's resources to deal with problems which, but for the shortcomings of the current computer system, could much more easily be overcome.

C-TPAT/FAST

Expedited Processing Benefits Should Be Extended. AAEI fully supports the proposal that food products subject to the FDA's Prior Notice requirements be eligible for the full expedited processing and information transmission benefits allowed with both the C-TPAT and FAST programs and, in fact, believes that integration of food companies and their products into the border security programs (and allowing access to their related benefits) is essential to the continued participation of the food industry as a whole in the C-TPAT and FAST programs. Moreover, AAEI does not believe that the security and verification processes in C-TPAT need to be modified in order to accomplish this critical goal for the food industry.

No access to related program benefits, especially for small to medium-sized companies, leads to the perception that spending time and resources on ensuring the security of their international supply chains is not worthwhile, efficient or effective. To have your supply chain verified as secure by Customs and Border Protection only to realize that 90–100% of your import shipments will not be afforded the expedited processing and other benefits supposedly allowed by these programs, simply because one is an industry that is also regulated by the FDA could be a considerable motivator for some companies to discontinue efforts to participate in these border security programs. If all of the shipments will be scrutinized upon arrival anyway because of FDA requirements, there is a high probability that some companies may conclude there is little to no incentive for spending resources on participating in these CBP programs.

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AAEI is aware that, historically, food companies have long been concerned about and accountable for the safety and security of their products without regard to the more recent border security programs implemented as a result of possible terrorist activities. It is vital to recognize that the issue of product integrity within the supply chain is already an integral part of the industry's own internal verification programs and a critical component of a company's brand protection. AAEI understands that food companies and those that import food-related products would not stay in business long if there were ever a question regarding the integrity and safety of their products. In addition, many food companies also participate in other, already established, FDA-implemented food safety programs designed to protect the public from food-related safety and quality concerns. All of these internal programs and food-related safety processes could be easily incorporated under the guidelines established for the program by CBP. As an example, production quality programs that address such areas as internal quality and food safety policies that apply to owned facilities, operations, employees, and products can easily be incorporated into the supplier section of the program summary. Such existing processes assist in providing for import products that are safe to use and consume through the point of manufacture and packaging at the producing facility.

Flexible Alternatives

Importers Require Flexible Approaches to Compliance. AAEI applauds the FDA's recognition that flexible approaches to Prior Notice submissions are an appropriate method to implement the Bioterrorism Act. Flexible alternatives are especially necessary when considering the provisions of the published Registration of Food Facilities interim final rule (68 FR 58894, October 10, 2003), which implements the statutory requirement for registration of all food facilities that manufacture or otherwise process food for consumption in the U.S. The provision places the burden to register on the owner, operator or agent in charge of that facility and provides that failure to register a facility is a prohibited act, which may not be cured by a party other than the owner, operator or agent in charge of the covered facility, unless that entity specifically designates another person to do so on its behalf.

As a practical matter, while food imported from an unregistered foreign facility is prohibited from entering the U.S., the FDA has no jurisdiction to enforce the registration requirements upon the affected foreign facilities. As a result, the Prior Notice requirements, as established in the interim final regulations, effectively shift the burden of ensuring foreign facility registration from the manufacturer, operator or agent to the importer. Accordingly, the importer suffers the loss of the goods, but is not authorized to cure the violation by registering the facility itself, unless specifically authorized to do so by the manufacturer, operator or agent in charge of that facility. If the party required by law to comply ignores the law, there is no reason to believe that party will cooperate with the U.S. importer to cure the deficiency. This rule applies to all importers, even those

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that have no relationship with the authorized parties. Thus, providing importers with flexible means to ensure entry of compliant food products is the appropriate method for facilitating continued trade in unadulterated food products without compromising the FDA's obligations under the Act.

Based upon the statutory obligation to maintain the confidentiality of information obtained as a result of facility registration, the FDA has determined that it cannot provide verification to food importers that a particular facility is registered prior to arrival of those goods at a U.S. port of entry. Although authorized registrants may provide that information to third parties, they are not prohibited from intentionally withholding that information so as to prevent importation by those they would like to prevent from buying, selling or importing their products – even if such actions result in violation of U.S. antitrust laws and other anti-competition regulations. This creates a new and unanticipated power in the hands of manufacturers, operators and their agents to control the distribution of food products without regard to their compliance with federal health and safety standards. As a result, American consumers could be deprived of competitively priced and distributed food articles and U.S. food producers deprived of the ability to import competitor's goods for critical sampling, testing, research and analysis.

Alternative Means for Ensuring Registration Should Be Sought. Considering the above possibilities, AAEI believes the FDA must consider alternative means for ensuring that all companies subject to the Registration of Food Facilities interim final rule (68 FR 58894, October 10, 2003) have an updated registration on file with FDA that has been verified. Taking such action will allow the FDA to ensure that the interim final regulations are not implemented in a manner that prevents the lawful import of safe and healthy food products based solely upon the unavailability of the confidential facility registration number.

We believe that the purposes of the Act can be fulfilled where the importer does not have access to the registration number: the identity of the manufacturer and country of origin should always be available in the Prior Notice, and the address of the manufacturing facility will often be available. In most instances, the FDA database should be sufficient to apprise the FDA whether one or more facilities are registered for the products in question; and inspection of goods can always be accomplished at the port of entry. Similarly, as the FDA considers providing preferential treatment to certain certified importers, it may also wish to exercise flexibility in its treatment of food importers that may not be in possession of confidential manufacturing facility registration numbers, but that voluntarily and willingly provide the agency with information sufficient to identify food source, manufacturer, country of export, shipper, and the other information required by statute and/or that may otherwise be reasonably necessary for the FDA to ensure compliance with existing U.S. law and regulations.

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AAEI is prepared to work with the FDA, the Congress and others in the private sector, to find a long-term and permanent solution to this significant commercial issue. We believe a regulatory or statutory solution can be developed and finalized by March, 2005, the date on which the FDA intends to publish its final rules. In the interim, we recommend again that the FDA modify its enforcement schedule to avoid the inevitable shut-down of importations by authorized or secondary market distributors and the importation of competitor's products for testing, sampling and analysis.

Conclusions and Recommendations

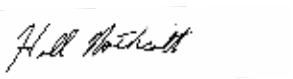
Reports of serious inconsistencies at multiple ports have been reported by AAEI members. The results have been confusion, delayed shipments and increased shipment costs. Some examples of inconsistent handling include: a shifting percentage of shipments that are physically held at the port due to incomplete or inaccurate Prior Notice submissions during the initial phases of enforcement, varying information regarding whether or not the carrier must be in possession of the actual Prior Notice confirmation number at the time of arrival regardless of whether or not the submission was made via an ABI transmission, conflicting information as to whether or not submissions of bonded freight will be allowed through the ABI system, and failure to notify importers of specific errors pertaining to their submissions.

In light of this situation, AAEI recommends and requests that the FDA offer a Prior Notice submission training program for submitters and transmitters, including brokers, in order to facilitate the accuracy and efficiency of the data being submitted under the regulations. Now that the process has been in place for a short period of time, we also recommend that additional internal training be provided to those individuals within the FDA and CBP who have responsibility for processing affected import shipments.

AAEI appreciates the opportunity to provide the FDA with these additional comments on the Interim Final Prior Notice rule. We sincerely hope that the concerns expressed in this correspondence, together with the suggested remedies, are helpful to the FDA in clarifying the issues before it.

Should you have any questions or concerns regarding this submission, please do not hesitate to contact us. We would welcome the opportunity to provide any additional information you may require.

Respectfully submitted,



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